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HOMEDICS®

510(k) Summary Statement

K001860

Submission Date: June 9, 2000

Contact: Michael Nelson
Quality & Facilities Manager
(248) 863-3000 ext. 1180 – tel.
(248) 863-3100 - fax

Classification Name: Paraffin Bath
Common/Usual Name: Paraffin Bath
Proprietary Name: ParaSpa™ Paraffin Bath
PAR-200
Classification: Class II

Description:

Full-size paraffin bath with an adjustable thermostat, which allows variable heat settings for custom comfort. There is a cool-to-the-touch plastic inner tub. Two LEDs are used to show there is power and that the thermostat is functioning. The unit has a power source of 120V, 60 Hz., 120 watts. The units are supplied with 60 plastic liners to lengthen the treatment time, and they include 6 pounds of pure paraffin wax. The units are packaged in conventional multi-colored gift boxes, and are marketed through consumer retail channels.

Intended Use:

- Useful in symptomatic relief of pain caused by arthritis, bursitis, and chronic joint inflammation.
- Relaxes muscles, relieves stiffness and muscle spasm.
- Stimulates circulation and for other conditions where heat is indicated.

Substantial Equivalence Claim:

The ParaSpa™ Paraffin Bath is substantially equivalent to the following models which are currently in distribution:

1. Para-Care® Paraffin Bath by Chattanooga Group, Inc. K980718
2. PARATherm® Bath by Grimm Scientific Industries K842423
3. Therabath® by WR Medical Electronics Co. none

Substantial equivalence is claimed because manufacturing technology, operating principles, intended uses and safety standards are the same for all models. Functional differences, i.e. adjustable thermostat, do not adversely affect safety or efficacy. Other differences are cosmetic in nature.

3000 Pontiac Trail
Commerce Township, MI 48390
Phone (248) 863-3000
Fax (248) 863-3100
Toll Free (800) 333-8282

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Mr. Micheal Nelson
Quality and Facilities Manager
Homedics, Inc.
3000 Pontiac Trail
Commerce Township, Michigan 48390

Re: K001860
Trade Name: ParaSpa™ Paraffin Bath
Regulatory Class: II
Product Code: IMC
Dated: June 9, 2000
Received: June 19, 2000

Dear Mr. Nelson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Barbara Zimmerman for CMW

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Applicant: HoMedics, Inc.

510(k) Number (if known): K001860

Device Name: ParaSpa™ Paraffin Bath

Indications For Use:

Useful in symptomatic relief of pain caused by arthritis, bursitis, and chronic joint inflammation.

Relaxes muscles, relieves stiffness and muscle spasm.

Stimulates circulation and for other conditions where heat is indicated.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

Barbara Hunnicutt for (MW)

(Division Sign-Off)

Division of General Restorative Devices

Number K001860

Over-the-Counter Use X